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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/641,142

08/15/2003

Steven Shraga

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

NOTIFICATION DATE

DELIVERY MODE

08/12/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/641,142	Applicant(s) SHRAGA, STEVEN	
	Examiner TUAN V. NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-33 and 35-48 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-14, 17-33 and 35-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/24/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In previous Office action claims 1-3, 8-14, 17-33 and 35-48 were examined and rejected and claims 4-7 have been withdrawn.
2. This Office action is in response to the amendment filed on 3/24/2009.

Response to Amendment

3. Applicant's arguments filed on April 24, 2009 with respect to claims 1-3, 8-14, 17-33, and 35-48 have been fully considered but they are moot in view of new ground of rejection.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 41 and 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Slama (US 4,469,110).**
6. Claims 41 and 42, both recite the limitations of “method” and “using the lancet device of claim 1” in the preamble. Nowhere in the body of the claims does the applicant positively claim providing the lancet device in claim 1, therefore, Examiner contends that the structure of the lancet device as claimed in claim 1 is

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not given weight because it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. Ex parte Pfeiffer, 1962 C.D. 408 (1961). Slama discloses (Figs. 1-4 and entire document) or in the alternative Slama inherently discloses the steps of: rotating the front cover 10 end to adjust the depth of penetration of the needle, moving the skin engaging end of lancet device against a user's skin, moving the holding member to a retracted position until the trigger is triggered, triggering the trigger 5 to cause the lancet needle to penetrate the user's skin,

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. **Claims 1-3, 8-14, 17-33, 35-42 and 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slama (US 4,469,110) in view of Schraga (US 6,156,051).**
10. Slama discloses (Figs. 1- 4 and col. 2, line 55 to col. 4, line 6) body 2 includes a marking 2b; trigger 5a; front cover 10, which includes indicia for the user to adjust the depth of penetration of the lancet; a holding member 3; main spring 4; first stop surface, which is the distal surface of holding member 3; second stop surface (see Fig. 4, the surface of front cover 10 that directly engaged with the distal surface of holding member 10); a back cap 5a; and wherein contact between the first and second stop surfaces defines a puncturing position of the lancet needle (Fig. 4 and col. 3, line 62 to col. 4, line 6). As to claims 43 and 45, Slama discloses the invention substantially as claimed except for the main spring disposed between the front and rear ends of the holding member. As to claim 44 , Slama discloses the invention substantially as claimed except for the main spring or first spring disposed between the front and rear ends of the holding member and a second spring disposed between the rear end of the holding member and surface of the back cap. However, Schraga discloses the holding member 30 should extend to the back end of the lancet device in order to enable to engage back cap 20b (Fig. 16) apparently in order to obtain the advantage of easily cocking the needle by pulling the back cap 20B (col. 14, lines 52-59) and a second spring should

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includes in the rear end of the holding member and a back cap (col. 14, lines 18-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the holding member and back cap as disclosed by Slama according to the teachings of Schraga by elongating the holding member 3 of Slama in the rearward direction to engage a similar back cap so that it too would have the same advantage.

11. Referring to claims 12, 18, 20, 21, 22, and 23, Schraga discloses the holding member comprises cylindrical surface and a polygonal cross-section shape and a deflecting member 37 is integrally formed with the holding member (Figs. 2 and 3A-3B). Apparently, the advantage of the polygonal cross-section is to prevent the shaft from rotating. It would have been obvious to one of ordinary skill in the art to modify the holding member of Slama according to the teaching of Schraga in order to gain the advantage of facilitating ease of triggering the device.
12. Referring to claim 25, Examiner contends that it would have been obvious to one of ordinary skill in the art to relocate the location of indicia from the outside surface of the front cover 10 to the outside surface of the body 2 and similarly, relocate the marking 2b to the outer surface of the front cover 10 because it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.
13. Referring to claim 36, Examiner contends that the device of Slama or Slama/Schraga comprises an ergonomic shape.

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14. Referring to claims 32, 33, 35 and 38, Schraga discloses the body is made from plastic material and is preferably molded of two halves to be joined together, so as to facilitate manufacture (col. 8, lines 28-33)

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **TUAN V. NGUYEN** whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731